



Threshold Pharmaceuticals Initiates Registrational Program of TH-070 for Treatment of Benign Prostatic Hyperplasia

U.S. Phase 2 Clinical Trials Underway

REDWOOD CITY, Calif., June 27, 2005 /PRNewswire-FirstCall via COMTEX/ -- Threshold Pharmaceuticals, Inc. (Nasdaq: THLD) announced today the initiation of its registrational program of its investigational drug candidate, TH-070 (lonidamine), under a U.S. Food and Drug Administration IND. The company has begun a U.S. Phase 2 clinical trial evaluating the dosing, safety and activity of TH-070 for the treatment of symptomatic benign prostatic hyperplasia (BPH). A Phase 3 multi-center European trial evaluating the safety and efficacy of TH-070 is expected to commence in mid 2005. BPH is a non-cancerous enlargement of the prostate that affects over 54 million men worldwide and at least 17 million men over the age of 40 in the United States.

The Phase 2 trial is a randomized, placebo controlled, double-blinded study that will be conducted at up to thirty centers across the United States. Approximately 200 patients will participate in the study for up to four and a half months. Patients will be randomized to receive placebo or one of four doses of TH-070 daily for 28 days, and will be followed off of therapy for an additional three months. The primary objective of this study is to investigate the dose-response relationship of TH-070 with respect to efficacy and safety.

Additionally, this study is designed to confirm the findings for 28 days of dosing previously announced by Threshold from a Phase 2 single center study conducted in 2004 at the University of Bari, Italy. That trial met its primary endpoint, a mean reduction in prostate volume measured by Trans-rectal Ultrasound (TRUS) at day 28 compared to baseline (-11.2%, p<0.001), and all other day 28 endpoints. Six months after cessation of treatment, BPH symptoms (International Prostate Symptom Scores) in patients remained significantly improved compared to baseline as were maximum urine flow, post-void urine volume, and PSA (Prostate Specific Antigen).

Detailed results of the study were published by MedReviews in the quarterly journal of Reviews in Urology. The information is available online at the MedReviews website <http://www.medreviews.com> .

"Our U.S. trial demonstrates Threshold's ability to launch a major clinical program in the BPH setting," said Alan Colowick, chief medical officer of Threshold. "We are excited about the potential that this therapy may offer men suffering from the symptoms of BPH while addressing the underlying disease itself. This trial complements a Phase 3 trial that will soon be initiated in Europe."

Both studies will investigate the effects of TH-070 on clinically important efficacy endpoints, including impact on symptoms as measured by IPSS, prostate volume measured by TRUS, change in PSA, change in maximal flow rate of urine, and a change in post-void residual of urine.

[Stock Info](#)

[SEC Filings](#)

[Corporate Governance](#)

[Investor FAQ](#)

[Contact Information](#)

[Event Calendar](#)

[News Releases](#)

[Webcasts](#)

[Email Alerts](#)

[Annual Reports](#)

[Information Requests](#)

[Analyst Coverage](#)

"The data thus far suggests that there is great promise for this treatment," said Dr. Claus Roehrborn, Chair of Urology at University of Texas, Southwestern and one of the lead investigators in the U.S. Phase 2 trial. "TH-070 has the potential to actually reverse the BPH process and bring relief to many men who suffer from this condition."

About TH-070 and Prostate Metabolism

TH-070 is thought to disrupt energy metabolism by interfering with glycolysis. Glandular prostate epithelial cells -- cells that overgrow in BPH -- are unique in that they are dependent on glycolysis for energy production. Preclinical data and Phase 2 data thus far supports that TH-070 presents a potentially effective method for targeting these prostate cells and may provide rapid symptom improvement, decreased prostate size, increase in urine flow, decreased serum PSA, with limited side effects for the treatment of BPH.

About Benign Prostatic Hyperplasia (BPH)

BPH, also known as benign enlargement of the prostate, is the most common urological problem among older men and affects an estimated 17 million men in the United States, 27 million men in five major European countries and 8 million men in Japan. BPH can restrict the flow of urine, resulting in urine retention, which can cause weakening of the bladder wall and the inability to empty the bladder completely. It can also be progressively severe, with the risk of urinary tract infection, kidney and bladder damage, bladder stones and incontinence. Current drug and surgical therapies for BPH are not very effective, often having slow onset and with side effects ranging from decreased libido, sexual dysfunction and reduced quality of life to cardiovascular effects and/or surgical complications.

About Threshold Pharmaceuticals

Threshold is a biotechnology company focused on the discovery, development and commercialization of small molecule therapeutics based on Metabolic Targeting, an approach that offers broad potential to treat most solid tumors and certain other diseases. The company is building a pipeline of drug candidates that selectively target tumor cells, offering the potential to be more effective and less toxic to healthy tissues than conventional drugs. Threshold's initial clinical focus is the treatment of cancer and benign prostatic hyperplasia, or BPH, a disease afflicting tens of millions of men worldwide. For additional information, please visit <http://www.thresholdpharm.com> .

This press release contains forward-looking statements regarding Threshold's TH-070 product candidate, clinical trial plans, anticipated clinical trial results, and the potential therapeutic benefits of TH-070 for BPH. These statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, Threshold's ability to initiate, enroll and complete its anticipated clinical trials, the results of such clinical trials (including unanticipated product side-effects or safety issues as well as efficacy data), the time and expense required to conduct such clinical trials, Threshold's ability to obtain regulatory approval for its product candidates based on such clinical trials and Threshold's ability to protect and enforce intellectual property rights regarding TH-070. Further information regarding these and other risks is included under the heading "Risk Factors" in Threshold's Quarterly Report on 10-Q, which was filed with the Securities Exchange Commission on May 13, 2005 and is available from the SEC's website (www.sec.gov) and on our website (www.thresholdpharm.com) under the heading "Investors". We undertake no duty to update any forward-looking statement made in this news release.

SOURCE Threshold Pharmaceuticals, Inc.

investors, Denise T. Powell of Threshold Pharmaceuticals, +1-650-474-8300, or

dpowell@thresholdpharm.com; or media, Kim Paone of Access Communications, +1-917-522-3528, or kpaone@accesspr.com, for Threshold Pharmaceuticals, Inc.

<http://www.prnewswire.com>

Copyright (C) 2005 PR Newswire. All rights reserved.

News Provided by COMTEX

©2004, THRESHOLD PHARMACEUTICALS. [TERMS OF USE](#) | [PRIVACY](#)

[HOME](#) [CONTACT](#) [DIRECTIONS](#) [SITE MAP](#)

[SEARCH](#)